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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,344	05/05/2006	Florence Henry	C 2892 PCT/US	6599
23657	7590	09/15/2009		
FOX ROTHSCHILD LLP 2000 MARKET STREET PHILADELPHIA, PA 19103			EXAMINER CHEN, CATHERYNE	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
			09/15/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

### Office Action Summary

**Application No.**

10/578,344

**Applicant(s)**

HENRY ET AL.

**Examiner**

CATHERYNE CHEN

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendments filed on Dec. 4, 2008 has been received and entered.

Currently, Claims 1-11 are pending. Claims 1-8 are examined on the merits.

The petition for suspension of action was granted for a period of six months from Dec. 31, 2008.

### ***Election/Restrictions***

Claims 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Feb. 28, 2008.

Applicant's election with traverse of Group I (Claims 1-8) and the species schizandrin and a stabilizer, in the reply filed on Feb. 28, 2008 is acknowledged.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 6, it is unclear what the component (b) should be because component (b) is in the singular form, while the "combinations of two or more" suggested not a singular component.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (1999, J Chromatographic Science, 37: 457-461).

Kim et al. teaches extraction of fruit of Schisandra chinensis by supercritical carbon dioxide and carbon dioxide modified with ethanol (Abstract). Extract of fruit of Schisandra chinensis would inherently contain the components schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid. Ethanol is an auxiliary solvent to extract components.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ikeda et al. (JP 06279256 A) with Newmark et al. (US 6242012 B1) providing evidence of inherent characteristics of Ikeda et al. for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Ikeda et al. teaches skin care cosmetics containing crude Chinese medicine of Gomishi extracted with water, skin lotion was prepared with glycerine (stabilizer) and refined water (additive) (Abstract). Schisandra chinensis is abbreviated as Schisandra,

which is known by the name Gomishi (see Specification, page 1, lines 22-31).

Sometimes Schisandra is spelled Schizandra. Crude Gomichi extract would inherently contain schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid because compounds in schizandra are called schizandrins (see Newmark et al., column 1, lines 46). The whole plant would contain the fruit because fruit is part of the plant.

The claims are drawn to a composition comprising schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid as the active ingredient therein, within a product-by-process claim.

The cited reference teaches a composition (including in pill/tablet form) consisting of (or consisting essentially of) an aqueous extract of *Schisandra chinensis* as the active ingredient therein which appears to be identical to (and thus anticipate) the presently claimed *Schisandra chinensis* extract composition (including inherently comprising the instantly claimed levels of schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid. Since both were prepared using similar aqueous extraction (including the same essential plant) and concentration steps, and both demonstrate the same/similar activity with respect to liver protection (see column 1, lines 14-15 and Applicant's Specification on page 2, lines 4-5). Consequently, the instantly claimed *Schisandra chinensis* extract composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed composition is not identical to the referenced *Schisandra chinensis* extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Schisandra chinensis* composition is likely to inherently possess the same characteristics of the claimed *Schisandra chinensis* composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed *Schisandra chinensis* composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., forming a topical or other commonly employed pharmaceutical form comprising a result-effective amount of the *Schisandra chinensis* extract beneficially taught by Ikeya et al. therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the *Schisandra chinensis* extract within Applicant's composition differ and, if so, to what extent, from the levels within the *Schisandra chinensis* extract disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that “the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process.” In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Applicant argues that there is unexpected superior performance from supercritical extraction.

In response to Applicant’s argument, there is no data to support the allegation. Applicant need to show that supercritical extract of Schisandra chinensis is better than other types of Schisandra chinensis extract. Thus, unexpected result is unpersuasive.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the



invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US 6242012 B1) in view of Kim et al. (1999, J Chromatographic Science, 37: 457-461).

Newmark et al. teaches schizandra has schizandrins (column 1, line 46), for oral administration or topical administration as a cream (column 3, lines 66-67), with conventional pharmaceutical carriers; aqueous powder or oily bases; thickeners and the like may be necessary or desirable (column 7, lines 41-47). Schizandra extract would intrinsically contain schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid.

However, it does not teach supercritical solvent extraction.

Kim et al. teaches extraction of fruit of *Schisandra chinensis* by supercritical carbon dioxide and carbon dioxide modified with ethanol (Abstract). Supercritical fluids have advantages of shorter extraction times, enhanced selectivity, and lack of residual solvent in the final extracts, nontoxic, environmentally acceptable (see Introduction, right column, paragraph 1). Ethanol is an auxiliary solvent to extract components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use supercritical solvent extraction because supercritical fluids have advantages of shorter extraction times, enhanced selectivity, and lack of residual solvent in the final extracts, nontoxic, environmentally acceptable (see Kim et al., Introduction, right column, paragraph 1). One would have been motivated to make extract with supercritical solvent for the expected benefit of nontoxicity and environmentally acceptable. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

The reference does not teach all the ingredients in one composition. However, the reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sung et al. (WO 01/41778 A1) and Newmark et al. (US 6242012 B1) in view of Kim et al. (1999, J Chromatographic Science, 37: 457-461).

Sung et al. teaches schizandrin extracted from schizandra (page 5, lines 19-21) with distilled water as stabilizer and methanol as an auxillary (page 6, lines 15, 20). The melanin synthesis inhibition compound of the present invention can be used a cosmetic

or pharmaceutical skin whitener (page 16, lines 6-9). Schizandra extract would intrinsically contain schizandrin, deoxyschizandrin, schisandrin C, gomisin A, gomisin N, pregomisin, and nordihydroguaiaretic acid (see Newmark et al., column 1, lines 46).

However, it does not teach supercritical solvent extraction.

Kim et al. teaches extraction of fruit of *Schisandra chinensis* by supercritical carbon dioxide and carbon dioxide modified with ethanol (Abstract). Supercritical fluids have advantages of shorter extraction times, enhanced selectivity, and lack of residual solvent in the final extracts, nontoxic, environmentally acceptable (see Introduction, right column, paragraph 1). Ethanol is an auxiliary solvent to extract components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use supercritical solvent extraction because supercritical fluids have advantages of shorter extraction times, enhanced selectivity, and lack of residual solvent in the final extracts, nontoxic, environmentally acceptable (see Kim et al., Introduction, right column, paragraph 1). One would have been motivated to make extract with supercritical solvent for the expected benefit of nontoxicity and environmentally acceptable. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

The references do not teach all the ingredients in one composition. However, the reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single

pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CATHERYNE CHEN** whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen  
Examiner Art Unit 1655

/Michael V. Meller/  
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